1-7 are currently under consideration pending the allowance of a generic claim. Claim 1 is an independent claim drawn to an encapsulated product with claims 2-7 depending therefrom and adding further limitations.

Claims 1-7 stand rejected under 35 U.S.C. §102(e) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Jerussi et al. (U.S. Patent No. 6,197,828). For the alternative obviousness rejection, the Examiner includes Amey et al. (U.S. Patent No. 6,245,350) for the inclusion of tablets into a capsule.

These remarks are presented in the expectation that they place this application in condition for allowance. Accordingly, entry of the remarks is respectfully requested.

Rejection of Claims 1-7 under 35 U.S.C 102(e) or 103(a)

Claims 1-7 stand rejected under 35 U.S.C. §102(e) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Jerussi et al. (U.S. Patent No. 6,197,828) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests

reconsideration and withdrawal thereof. To establish an anticipation rejection, every claimed element must be found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); *See also*, MPEP § 2131. Applicant respectfully submits that the Jerussi et al. patent does not teach every claimed element found in independent claim 1, and therefore fails to anticipate the claim and dependent claims 2-7 which necessarily contain the elements of claim 1.

Independent claim 1 is drawn to an encapsulated product comprising a therapeutically effective amount of a pharmaceutical, at least one compressible material, and at least one lubricating material. The encapsulated product is **in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters.** Applicant respectfully submits that the Jerussie et al. patent does not disclose each and every limiation.

The Jerussi et al. patent (U.S. Patent No. 6,197,828) discloses methods of preparing, and compositions comprising, derivatives of (+) venlafaxine. The dosage form may include tablets, caplets, troches, lozenges, dispersions, suspensions, suppositories, ointments, cataplasms, pastes, powders, dressings,

creams, plasters, solutions, capsules, soft elastic gelatin capsules, and patches.

Applicant respectfully submits, however, that the Jerussi et al. patent **fails to disclose the dosage form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters**. This important limitation is found in independent claim 1, and thus also in the dependent claim, and since the Jerussi et al. patent **fails to disclose this limitation**, Applicant submits that the Jerussi et al. patent **fails to anticipate claims 1-8**, since the reference needs to disclose each and every claimed limitation in order to anticipate the claims.

Thus, since it is apparent that the Jerussi et al. patent **fails to disclose each and every limitation found in independent claim 1**, Applicant respectfully submits that the Jerussi et al. patent therefore **does not anticipate claim 1** under 35 U.S.C. 102(e).

Turning to the alternative rejection under 35 U.S.C. 103(a), Applicant respectfully traverses this rejection. Applicant respectfully submits that the references of record, the Jerussi et al. patent and the Amey et al. patent, do not teach or suggest Applicant's inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this

reference that would lead one of ordinary skill in the art to modify the reference to arrive at the subject of the amended claims with any expectation of success at the time the invention was made.

The U.S. Supreme Court in Graham v. John Deere Co., 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

A. The present inventive subject matter

As is stated above, independent claim 1 is drawn to an encapsulated product comprising a therapeutically effective amount of a pharmaceutical, at least one compressible material, and at least one lubricating material. The encapsulated product is **in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters**. The remaining claims depend from claim 1 and add further limitations thereto.

B. The prior art

The Jerussi et al. patent (U.S. Patent No. 6,197,828) discloses methods of preparing, and compositions comprising, derivatives of (+) venlafaxine. The dosage form may include tablets, caplets, troches, lozenges, dispersions, suspensions, suppositories, ointments, cataplasms, pastes, powders, dressings, creams, plasters, solutions, capsules, soft elastic gelatin capsules, and patches.

The Amey et al. patent (U.S. Patent No. 6,245,350) discloses a process for encapsulation of caplets in a capsule and solid dosage forms obtainable by the process. The Amey et al. patent discloses a process for encapsulation of a caplet in a capsule by

cold shrinking together capsule parts, which are filled with the caplets.

C. The differences between the claimed subject matter and the prior art

The differences between applicant's inventive subject matter and the cited reference is apparent from their independent and distinct disclosures and claim. Claim 1 (and the claims which depend therefrom) claim an encapsulated product **in the form of a caplet having a diameter from about 1 millimeter to about 7 millimeters and a length from about 1 millimeter to about 7 millimeters**. As is discussed at length above, Applicant respectfully submits that the Jerussi et al. patent **does not disclose this limitation**.

The Examiner turns to the Amey et al. patent for the proposition that the caplets may be encapsulated in a capsule. However, Applicant respectfully submits that the Amey et al. patent **fails to cure the deficiency** of the Jerussi et al. patent. In other words, Applicant respectfully submits that the Amey et al. patent also **does not disclose** the limitation regarding the size of the caplets as claimed in the present claims under consideration.

Thus, assuming *arguendo*, that the Jerussi et al. patent and

the Amey et al. patents were combined in an attempt to achieve the presently claimed subject matter, Applicant respectfully submits that the combination of the patents **would still not disclose** all of the limitations of the present claims. In particular, the combination of the patents would not include the limitation regarding the size of the caplets.

Since this deficiency would still be present, Applicant respectfully submits that the Examiner has failed to prove a *prima facie* case of obviousness, which requires that the prior art references teach or suggest all of the claimed limitations. It is clear that the prior art references cited by the Examiner fail to accomplish this, and thus the claims are not obvious over the references. Applicant, therefore, respectfully request reconsideration and withdrawal of the alternative obviousness rejection.

Accordingly, Applicant respectfully submits that the present inventive subject matter, as claimed in claims 1-8, is not anticipated by the Jerussi et al. patent, nor is it rendered obvious by the combination of the Jerussi et al. patent with the Amey et al. patent. Applicant request reconsideration and withdrawal of these rejections.

CONCLUSION

In view of the foregoing, Applicant respectfully submits that the present claims are patentable over the prior art of record in this case and requests the Examiner to reconsider and withdraw the rejection of the claims and to allow all of the claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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